

REMARKS

Claims 16-17 and 28-33 are active. Claims 18-27 have been cancelled. Claim 16 has been amended to further define the propellant and cosolvent. Support is found in the original claims and on page 13, lines 8-14, of the specification. Accordingly, the Applicants do not believe that any new matter has been added.

Objection

Claim 16 was objected to as containing a typographical error. This objection is now moot.

Rejection—35 U.S.C. §112, second paragraph

Claims 16, 17 and 33 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Rejection—35 U.S.C. §102

Claims 16-21, 23-27, 29 and 31-33 were rejected under 35 U.S.C. 102(b), as being anticipated by McNally et al., U.S. Patent No. 5,653,961. McNally does not disclose an aerosol having the physical characteristics required by Claim 16. Namely, there is no disclosure of an aerosol having an MMAD greater than 2 $\mu$ m, wherein at least 40% of said aerosol is composed of fine particles having a diameter of less than 4.7 $\mu$ m.

In order to replace undesirable propellants, such as environmentally unfriendly CFC's, the inventors sought a way to make an aerosol suitable for pulmonary administration using propellants other than CFC's, e.g., aerosol particles having a similar size characteristics to those produced using CFC propellants. To do this, the present inventors found out how to

modulate and control the MMAD of aerosol particles while simultaneously providing an aerosol having a high fraction (>40%) of fine particles able to reach the peripheral regions of the lung. The inventors discovered that the MMAD could be modulated by using different ratios of HFA 227 and HFA 134a. McNally is totally silent with respect to how to modulate the MMAD by varying the ration of these propellants. Moreover, McNalley provides no reasonable expectation of success that varying the ratio of these two propellants would produce an aerosol having the desirable characteristics of that of the invention.

On the other hand, the present inventors have discovered that by varying the proportions of HFA 227 and HFA 134a that the aerosols (specification, page 8, line 23 ff.) having an MMAD suitable for pulmonary administration are produced. For example, the present invention permits control of the MMAD which permits an aerosol to deliver the active ingredient to the appropriate parts of the respiratory tract (specification, page 6, lines 6-9) and on the other hand to avoid systemic absorbtion of the active ingredient from particles which are too small (specification, page 8, lines 12-22). Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §103

Claim 22 was rejected under 35 U.S.C. 103(a), as being unpatentable over McNally et al., U.S. Patent No. 5,653,961. McNalley does not render the invention obvious for the reasons discussed above. That is, it does not suggest the aerosols of the present invention nor show how to produce them by modulating HFA 227 and HFA 134a content.

Rejection—35 U.S.C. §103

Claims 28 and 30 were rejected under 35 U.S.C. 103(a), as being unpatentable over McNally et al., U.S. Patent No. 5,653,961, as applied to Claim 22 above, and further in view of Byron et al., U.S. Patent No. 5,190,029. McNally does not render the invention obvious for the reasons discussed above. That is, it does not suggest the aerosols of the present invention, nor show how to produce them. Byron also does not disclose or suggest aerosols having the physical characteristics of those of the invention, nor teach how to make such aerosols. Thus, the Applicants request respectfully that this rejection be withdrawn.

Rejection—35 U.S.C. §103

Claims 16-24 and 27-32 were rejected under 35 U.S.C. 103(a), as being unpatentable over Keller et al., WO 98/34595 (U.S. equivalent U. S. Patent 6,461,591). Keller does not disclose or suggest the invention, because the Keller propellant contains carbon dioxide. The present claims are directed to propellants consisting of HFA 227 and HFA 134a. Moreover, Keller does not disclose or suggest an aerosol having the physical characteristics of the aerosol of the invention, nor suggest how to make such an aerosol using a propellant consisting of only HFA 227 and HFA 134a. Keller is totally silent about modulating aerosol characteristics by varying the content of these two propellants. Accordingly, this rejection may now be withdrawn.

Rejection—Double Patenting

Claims 16-33 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-12, 14 and 16-29 of U.S. Patent No. 6,713,047. The Applicants respectfully request that this rejection be held in abeyance pending the

identification of otherwise allowable subject matter. At that time, if necessary, a terminal disclaimer may be filed.

Rejection—Double Patenting

Claims 16-24, 27 and 30-32 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-14 and 22-24 of U.S. Patent No. 6,964,759. The Applicants respectfully request that this rejection be held in abeyance pending the identification of otherwise allowable subject matter. At that time, if necessary, a terminal disclaimer may be filed.

Provisional Rejections—Double Patenting

Present pending claims were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over various claims of copending applications 09/831,888, 10/204,307, 10/244,519, 10/275,891, 10/290,225, 10/435,032 and 10/435,354. The Applicants understand that these provisional rejections will be withdrawn upon an indication of allowability for this application, if none of the copending application have yet been allowed. Accordingly, they respectfully request that these provisional rejections be held in abeyance pending the identification of otherwise allowable subject matter.

Application No.: 10/766,857

Response to Official Action of January 18, 2006

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, reading "Thomas M. Cunningham". The signature is fluid and cursive, with the first name "Thomas" being more prominent and the last name "Cunningham" written in a continuous script.

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